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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,852	01/17/2001	Kjell Olmarker	003300-712	9070

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EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/23/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,852

Applicant(s)

OLMARKER ET AL.

Examiner

Eileen B. O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-57 is/are pending in the application.
- 4a) Of the above claim(s) 52-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 35-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 7. 6) ☐ Other:

DETAILED ACTION

Advisory Information

1. The numbering of claims is not in accordance with 37 CFR 1.126, which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). In the claims entered in preliminary Amendment A, Paper No. 3 filed Jan. 17, 2001, there was no claim 40. Therefore, misnumbered original claim 41 was renumbered as 40, and all successive claims were also renumbered correspondingly. Applicants should note that newly numbered claims 48 and 49 now depend from claim 47, and newly numbered claim 51 depends from claim 50.

Claims 35-57 are pending in the instant application.

Election/Restrictions

2. Applicant's election with traverse of Group I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that all claims could be conveniently prosecuted in a single application, and during the international phase of examination unity of invention already has been confirmed. Applicants further regard all the TNF- α inhibitors and all the nerve disorders, respectively, to constitute a single inventive concept and that all generic claims should accordingly be allowable. This is not found persuasive because although a lack of unity was not found in the international application, this does not preclude a lack of unity found in the United States application. The two groups do not related to a single general concept under PCT Rule

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13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature, because pharmaceutical compositions comprising TNF- α inhibitors were well known in the art and therefore cannot constitute a unifying technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 52-57 are withdrawn as being drawn to a non-elected invention.

Claims 35-51 are currently under examination.

Priority Statement in First Line in Specification

3. The priority statement added under CROSS-REFERENCED APPLICATIONS on page 1 of the Amendment filed Jan. 17, 2001 should be deleted, because applications filed under 371 should not have this information in the specification. (Additionally, some of the priority information is duplicated in the Amendment).

Priority

4. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Sweden on Sept. 25, 1998. It is noted, however, that applicant has not filed a certified copy of the 9803276-6 application as required by 35 U.S.C. 119(b).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-18 of copending Application No. 09/760,811. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass methods of nerve disorders or injuries by administration of compounds that inhibit the activity of TNF- α .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Specification

- 6.0 The disclosure is objected to because of the following informalities:
- 6.1 The first complete sentence on page 5 is grammatically incorrect and does not make sense.
- 6.2 On page 6, line 20, in the term "100 gl", it is not clear what "gl" stands for.
- 6.3 On page 6, line 20, "1,11" should be "1.11".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 35-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7.1 The claims are indefinite because in the first line of claim 35 the method recites "treating nerve disorders", and in the last line recites "inhibits nerve injury", which is different from a nerve disorder.

7.2 The claims are also indefinite because of the recitation in claim 35 in parts (i-iii) of "that blocks TNF- α ", and it is not clear what "blocks" means. It would clarify the claim if the word "activity" were inserted after the word "TNF- α ".

Conclusion

8. No claim is allowed.

9. The art considered pertinent to the present application is Tobinick, PN 6,177,077, and Tobinick et al., PN 6,015,557, (cited by Applicants) which disclose a method of inhibiting the action of TNF for treatment of neurological disorders and diseases including neurological traumas and injuries including spinal cord injury, spinal cord compression and herniated discs. This is not considered prior art since the priority date of the instant application is before that of the issued patents.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

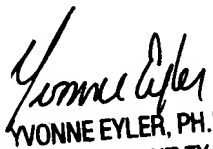
Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600